

RECEIVED
CENTRAL FAX CENTER
NOV 17 2008

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted by facsimile to the Patent and Trademark Office, facsimile no. (571) 273-8300 at MS Patent Extension, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: November 17, 2008 Signature: *Madhavi Richmond*

(Madhavi L. Richmond, Ph.D.)

Docket No.: MXI-321CPRCE
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Letters Patent of:
Vincent Dubois *et al.*

Confirmation No.: 3549

Patent No.: 7425541 B2

Art Unit: 1654

Issued: September 16, 2008

Examiner: A.D. Kosar

For: ENZYME-CLEAVABLE PRODRUG
COMPOUNDS

MS Patent Extension
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**APPLICATION FOR PATENT TERM ADJUSTMENT INCLUDING REQUEST FOR
RECONSIDERATION UNDER 37 CFR §1.705(d)**

Dear Sir:

1. This is a request for reconsideration of the patent term adjustment of the patent term adjustment of 703 days listed on the cover page of the above-identified patent. It is respectfully requested that Patentees be granted a patent term adjustment of 1342 days.
2. This request for reconsideration is being filed within two months of the issue date of the patent (September 16, 2008) and includes the following documents, as required under 37 CFR §§ 1.705(b)(1) and (b)(2):
 - a. The fee set forth in 37 CFR §1.18(e); and
 - b. A "Statement under 37 CFR §1.702(b)(2)," which specifies the correct patent term adjustment and the bases under 37 CFR §1.702 for the adjustment; the relevant dates under 37 CFR §§ 1.703(a) through (e) for which adjustment is sought; the adjustment specified in 37 CFR §1.703(f) to which the patent is entitled; and whether the patent is subject to a terminal disclaimer and any

11/18/2008 VBUI22 00000002 120000 09879442

01 FC:1455 200.00 DA

Patent No.: 7425541 B2

Docket No.: MXI-321CPRCE

expiration date specified in the terminal disclaimer.

3. Patentees note that this request for reconsideration does not raise any issues that were raised, or could have been raised, in an application for patent term adjustment under 37 CFR §1.702(b).

Dated: November 17, 2008

Respectfully submitted,

By: Meaghan L. Richmond
Meaghan L. Richmond, Ph.D.
Registration No.: 61,402
LAHIVE & COCKFIELD, LLP
One Post Office Square
Boston, Massachusetts 02109-2127
(617) 227-7400
Agent For Patentees

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted by facsimile to the Patent and Trademark Office, facsimile no. (571) 273-8300 at MS Patent Extension, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: November 17, 2008 Signature: Madhavi Richmond

(Madhavi L. Richmond, Ph.D.)

RECEIVED
CENTRAL FAX CENTER
NOV 17 2008

Docket No.: MXI-321CPRCE
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Letters Patent of:
Vincent Dubois *et al.*

Confirmation No.: 3549

Patent No.: 7425541 B2

Art Unit: 1654

Issued: September 16, 2008

Examiner: A.D. Kosar

For: ENZYME-CLEAVABLE PRODRUG
COMPOUNDS

MS Patent Extension
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

STATEMENT UNDER 37 CFR §1.702(b)(2)

Dear Sir:

1. This statement is respectfully submitted in support of the "Application for Patent Term Adjustment Including Request for Reconsideration under 37 CFR §1.705(d)" for the above-identified patent. In view of the following, it is respectfully requested that Patentees be granted a minimum patent term adjustment of 1342 days.
2. The patent term adjustment on the "Determination of Patent Term Adjustment under 35 U.S.C. §1.54(b)" as shown on the face of the issued patent is 703 days. The determination of 703 days is in error in that, pursuant to 35 U.S.C. §154(b), the Office:
 - (a) failed to issue a patent within three years of the actual filing date of the above-identified application in accordance with 37 CFR §1.703(b); and
 - (b) failed to reduce the period of the term of the patent due to Patentees' delay under 37 CFR §1.704(b).
3. The factual bases for the above adjustment are set forth as follows:
 - A. Examination Delays Pursuant to 37 CFR §1.702 and §1.703Pursuant to 37 CFR §1.703(f), the period of adjustment of the term of the patent under §1.702 is

Patent No. 7425541 B2

Docket No.: MXI-321CPRCE

the sum of the periods of examination delay calculated under subparagraphs (a)-(e), to the extent that such periods are not overlapping, less the sum of the periods calculated under §1.704 (the period of Applicant Delay). In the above-identified patent, Patentees are entitled to a period of examination delay equal to the sum of the periods of delay under §1.702(b) and §§1.703(a)(1) and (b)(1) for the reasons set forth below.

(i) "14 Month Delay" Pursuant to 37 CFR §1.703(a)(1)

In accordance with 37 CFR §1.703(a)(1), Patentees are entitled to a period of patent term adjustment due to the failure by the Office to mail an action under 35 U.S.C. §132 not later than 14 months after the actual filing date (hereinafter "the 14 Month Delay"). Specifically, Patentees are entitled to a period of patent term adjustment beginning on the day after the date that is 14 months after the date on which the above-identified patent was filed under 35 U.S.C. §111(a), i.e., June 11, 2001, and ending on the date of mailing of an action under 35 U.S.C. §132, i.e., a Restriction Requirement mailed May 26, 2004. Accordingly, the period of patent term adjustment due to the 14 Month Delay by the Office is 654 days, which is in agreement with the period calculated by the Office on the PTA Calculation Sheet, enclosed herewith as Appendix A.

(ii) "Three Years Delay" Pursuant to 37 CFR §1.702(b) and §1.703(b)(1)

Pursuant to 37 CFR §1.702(b), Patentees are entitled to a period of delay due to the failure of the Office to issue a patent within three years after the date on which the application was filed under 35 U.S.C. §111(a). Patentees note that the Office failed to comply with the Requirement under 37 CFR §1.702(b), and therefore, Patentees have calculated a maximum of Three Years Delay of 1101 days based on the period of time beginning on the day after the date that is three years after the date on which the above-patent was filed under 35 U.S.C. §111(a) (i.e., June 11, 2004) and the date that the patent issued (i.e., September 16, 2008). However, as set forth in 37 CFR §1.703(b)(1), the Three Years Delay Requirement does not include the period consumed by continued examination of the application under 35 U.S.C. §132(b), beginning on the date on which a request for continued application of the application under 35 U.S.C. §132(b) was filed and ending on the date the patent was issued. Patentees note that a request for continued examination under 35 U.S.C. §132(b) was filed on June 18, 2007, and therefore, 457 days of patent term due to the request for continued examination is excluded from this calculation (i.e., the days between the date of the filing of the request for continued examination and the date the patent was issued, i.e., September 16, 2008).

Patent No. 7425541 B2

Docket No.: MXI-321CPRCE

(iii) Total Examination Delay Pursuant to 37 CFR §1.703(f)

As set forth in 37 CFR §§1.703(f), the period of examination delay based on the groups set forth in 37 CFR §1.702 is the sum of the period of the 14 Month Delay (654 days) and the maximum period of the Three Years Delay (1101 days), or 1755 days, to the extent these periods of delay are not overlapping. As the period of the 14 Month Delay ended on August 11, 2002, prior to the first day of the period of the Three Years Delay (*i.e.*, June 11, 2004), Patentees submit that these periods are not overlapping.

B. "Applicant Delay" Pursuant to 37 CFR §1.704

Pursuant to 37 CFR §1.704(b), the period of adjustment shall be reduced for the period in excess of three months taken to reply to any Office notice or action making any rejection, objection, argument or other request, beginning on the day after the date that is three months after the date of mailing of the Office communication and ending on the date the reply was filed (hereinafter "Applicant Delay"). As indicated on the Office's PTA Calculation Sheet (Appendix A), the Office has calculated a period of Applicant Delay of 399 days. However, as described below, Patentees calculate a total period due to Applicant Delay as 413 days, which is inconsistent with the period calculated by the Office.

(i) Applicant Delay Due to Response to Notice to File Missing Parts

On July 26, 2001, the Office mailed a Notice of Missing Parts of Nonprovisional Application under 37 CFR §1.53(b) for the above-identified patent requiring an oath or declaration of inventors in compliance with 37 CFR §1.63, an \$130 surcharge as set forth in 37 CFR §1.16(e), a substituted computer readable form (CRF) copy of the "Sequence Listing" and a statement pursuant to 37 CFR §§1.821(e), (f) or (g), §1.825 (b) or (e), as shown in Appendix B. Patentees responded to this Notice of Missing Parts on November 9, 2001 by filing the appropriate executed declarations, the surcharge, a petition of extension of time, the substitute CRF copy of the "Sequence Listing," the statement pursuant to 37 CFR §§1.821(e), (f) or (g), §1.825 (b) or (e), and the appropriate fees.

However, Patentees note that, pursuant to 37 §1.704(b), the Office failed to reduce the period of adjustment by 14 days, which is the period in excess of three months taken for Patentees to reply to the Notice of Missing Parts, *i.e.*, October 26, 2001 through November 9, 2001.

Patent No. 7425541 B2

Docket No.: MXI-321CPRCE

(ii) Total Applicant Delay

Accordingly, Patentees calculate that the total period of Applicant Delay is 413 days, which includes the period of 399 days calculated by the Office for Applicant Delay and the period of 14 days the Office failed to reduce the period of adjustment as a result of Applicant Delay Due to the Response to Notice to File Missing Parts.

C. Calculation of Correct Patent Term Adjustment Pursuant to 37 CFR §1.702(f)

As set forth in 37 CFR §1.703(f), Patentees are entitled to a period of patent term adjustment equal to the period of examination delays reduced by the period of Applicant Delay. Therefore, Patentees submit that the correct patent term adjustment for the above-referenced patent is 1342 days, which is the difference between the total period of examination delay (1755 days) and Applicant Delay (413 days).

4. An accordance with 37 CFR §1.705(b)(2)(iii), Patentees submit that this patent is not subject to a terminal disclaimer.

Dated: November 17, 2008

Respectfully submitted,

By: 

Meaghan L. Richmond, Ph.D.

Registration No.: 61,402

LAHIVE & COCKFIELD, LLP

One Post Office Square

Boston, Massachusetts 02109-2127

(617) 227-7400

Agent For Patentees

Patent No. 7425541 B2

Docket No. MXI-321CPRCE

APPENDIX A

09/879,442 ENZYME-CLEAVABLE PRODRUG COMPOUNDS

Patent Term Adjustments			
Patent Term Adjustment (PTA) for Application Number: 09/879,442			
Filing or 371(c) Date:	06-11-2001	USPTO Delay (PTO) Delay (days)	1102
Issue Date of Patent:	09-16-2008	Three Years:	-
Pre-Issue Petitions (days)	+0	Applicant Delay (APPL) Delay (days)	399
Post-Issue Petitions (days)	+0	Total PTA (days)	703
USPTO Adjustment (days)	+0	Explanation Of Calculations	

Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL(Days)
08-27-2008	PTA 36 Months	448	
09-16-2008	Patent Issue Date Used in PTA Calculation		
08-14-2008	Dispatch to RBC	0	
08-14-2008	Application Is Considered Ready for Issue	0	
08-11-2008	Issue Fee Payment Verified	0	
08-11-2008	Issue Fee Payment Received	0	
05-23-2008	Sequence Forwarded to Pub on Tape	0	
05-13-2008	Mail Notice of Allowance	0	
05-12-2008	Notice of Allowance Data Verification Completed	0	
05-12-2008	Case Docketed to Examiner in GAI	0	
05-12-2008	Document Verification	0	
05-12-2008	Examiner's Amendment Communication	0	
05-08-2008	Examiner Interview Summary Record (PTOL - 413)	0	
03-09-2008	Data Forwarded to Examiner	0	
02-07-2008	Response after Non-Final Action		62
02-07-2008	Request for Extension of Time - Granted	0	
01-16-2008	Mail Examiner Interview Summary (PTOL - 413)	0	
01-08-2008	Examiner Interview Summary Record (PTOL - 413)	0	
09-07-2007	Mail Non-Final Rejection	0	

Patent No. 7425541 B2

Docket No. MXI-321CPRCE

09-04-2007	Non-Final Rejection	
11-30-2001	Information Disclosure Statement considered	
11-30-2001	Information Disclosure Statement (IDS) Filed	
06-18-2007	Affidavit(s) (Rule 131 or 132) or Exhibit(s) Received	
06-22-2007	Date Forwarded to Examiner	
06-22-2007	Date Forwarded to Examiner	
06-18-2007	Request for Continued Examination (RCE)	62
06-22-2007	DISPOSAL FOR A RCE/CPA/129 (express abandonment I.C.P.A.)	6
06-18-2007	Request for Extension of Time - Granted	46
06-18-2007	Workflow - Request for RCE - Begin	46
06-01-2007	Mail Examiner Interview Summary (PTOL - 413)	6
05-24-2007	Examiner Interview Summary Record (PTOL - 413)	46
01-17-2007	Mail Final Rejection (PTOL - 126)	46
01-08-2007	Final Rejection	
10-17-2006	Date Forwarded to Examiner	
10-05-2006	Response after Non-Final Action	92
10-05-2006	Request for Extension of Time - Granted	3
10-13-2006	CRF Is Good Technically / Entered into Database	46
11-28-2006	CRF Is Good Technically / Entered into Database	46
06-29-2006	CRF Is Flawed Technically / (Not Entered into Database)	46
04-10-2006	Correspondence Address Change	46
04-05-2006	Mail Non-Final Rejection	46
04-03-2006	Non-Final Rejection	
01-24-2006	Date Forwarded to Examiner	
01-03-2006	Response after Non-Final Action	94
01-03-2006	Request for Extension of Time - Granted	46
07-01-2005	Mail Non-Final Rejection	46
06-27-2005	Non-Final Rejection	

Patent No. 7425541 B2

Docket No. MXI-321CPRCE

05-12-2005	Date Forwarded to Examiner	
05-04-2005	Response after Non-Final Action	89
05-04-2005	Request for Extension of Time - Granted	9
12-14-2004	Correspondence Address Change	9
12-14-2004	Change in Power of Attorney (May Include Associate POA)	9
12-07-2004	Miscellaneous Incoming Letter	9
11-04-2004	Mail Non-Final Rejection	9
11-01-2004	Non-Final Rejection	
09-09-2004	Date Forwarded to Examiner	
08-26-2004	Response to Election / Re-election Filed	
08-26-2004	Request for Extension of Time - Granted	
08-26-2004	Workflow incoming amendment IFW	
05-25-2004	Mail Restriction Requirement	654
05-25-2004	Requirement for Restriction / Election	9
05-05-2004	Case Docketed to Examiner in GAU	9
04-19-2004	Case Docketed to Examiner in GAU	9
04-15-2004	Transfer Inquiry to GAU	9
03-22-2003	IFW ISS Processing by Tech Center Complete	9
03-06-2003	Correspondence Address Change	9
03-06-2003	Mail Record Petition Decision of Granted Related to Attorney	9
12-31-2002	Petition Entered	9
10-04-2002	Case Docketed to Examiner in GAU	9
09-18-2002	Information Disclosure Statement (IDS) Filed	9
09-18-2002	Information Disclosure Statement (IDS) Filed	9
06-15-2002	Case Docketed to Examiner in GAU	9
12-19-2001	Case Docketed to Examiner in GAU	9
12-05-2001	Application Dispatched from OIPE	9
12-03-2001	Application is Now Complete	9
07-26-2001	Notice Mailed - Application Incomplete - Filing Date Assigned	9
07-26-2001	Correspondence Address Change	9

Patent No. 7425541 B2

Docket No. MXI-321CPRCE

06-21-2001	IPW Scan & PACR Auto Security Review	10
06-11-2001	CRF Disk Has Been Received by Preexam Group / PGT	10
06-11-2001	Initial Exam Team	10